IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE MYLAN N.V. SECURITIES LITIGATION	)	2:20-cv-955-NR

OPINION

In this putative securities class action, Lead Plaintiff Public Employees' Retirement System of Mississippi sues Defendants Mylan N.V., CEO Heather Bresch, President Rajiv Malik, and CFO Kenneth Parks under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder. Defendants move to dismiss the amended complaint for failure to state a claim. For the reasons below, Defendants' motion to dismiss will be granted in part and denied in part.

FACTUAL BACKGROUND

I. Regulatory environment for Mylan's core business.

As pled in the amended complaint, Mylan is one of the largest generic drug manufacturers in the world. ECF 39, ¶ 2. Mylan has fifty manufacturing facilities worldwide, sixteen of which are in North America. *Id.* at ¶ 281. One of those North American facilities is in Morgantown, West Virginia. *Id.* at ¶ 1. The Morgantown facility accounted for roughly 85% of the tablets and gel capsule drugs that Mylan sold in the United States each year during what is defined as the "class period" (February 16, 2016, through May 7, 2019). *Id.* at ¶¶ 7, 34.[1]

Mylan operates in a heavily regulated industry, and, as a result, its success and reputation depends on producing safe and efficacious products. *Id.* at ¶¶ 26, 35,

[1] Mylan, as a corporate entity, no longer exists. In November 2020, it merged with Upjohn Co. to now form Viatris Inc. ECF 46, p. 1 n.1.

43. Drug manufacturers like Mylan must comply with FDA quality control regulations, including Current Good Manufacturing Practices ("CGMP"). *Id.* at ¶¶ 2, 43. The FDA relies on manufacturers to conduct testing (and implement data quality controls to validate that testing), since the FDA cannot test every drug distributed in the U.S. *Id.* at ¶¶ 44, 54. If drugs fail testing, manufacturers are prohibited from re-testing them to achieve a passing result, because doing so could conceal the production of unsafe drugs. *Id.* at ¶¶ 49-50.

As another safeguard to ensure compliance with CGMP requirements, the FDA conducts periodic inspections of drug manufacturing facilities. *Id.* at ¶ 52. Those inspections can result in the issuance of a "Form 483," which is a report setting forth "conditions that in [the FDA inspector's] judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act[.]" ECF 47-10, FDA 483, FAQs. But this Form only lists inspectional observations and "does not constitute a final Agency determination of whether any condition [at a facility] is in violation of the FD&C Act[.]" *Id.* Manufacturers, like Mylan, are encouraged to respond to any issues noted in a Form 483 that they receive. ECF 47-1, p. 1.

The FDA may follow up on Form 483 inspectional observations by issuing an untitled letter or a "Warning Letter." ECF 39, ¶ 152. Untitled letters document less significant issues and do not "warn" about potential enforcement actions. ECF 47-12. Warning Letters are reserved for more "significant violations" that "may lead to an enforcement action if not promptly and adequately corrected." ECF 47-13.

At all relevant times, Mylan recognized that "failure to comply with CGMP" could result in a host of serious regulatory sanctions, including "warning letter[s], fines, penalties, disgorgement, unanticipated compliance expenditures," product recalls, and even criminal prosecution. ECF 39, ¶ 56.

II. Inspection of Mylan's Nashik facility.

In September 2016, the FDA inspected Mylan's facility in Nashik, India. ECF 39, ¶ 91. After that inspection, the FDA issued a Form 483 to Mylan, documenting a series of safety and data failures. *Id.* at ¶¶ 91-93; ECF 39-3, pp. 1-4. Later, the FDA issued a Warning Letter to Mylan about the issues observed during the inspection. ECF 39, ¶ 146. Mylan publicly acknowledged the letter. *Id.* at ¶ 277. The FDA eventually issued a "Closeout Letter," stating that it "had completed an evaluation of [Mylan]'s corrective actions" and "it appears that [Mylan has] addressed the violations contained in th[e] [Nashik] Warning Letter." ECF 47-4.

III. Inspections of Morgantown facility.

In November 2016, the FDA inspected Mylan's facility in Morgantown, West Virginia. ECF 39, ¶ 95. Once again, after that inspection, the FDA issued a Form 483 to Mylan. *Id.* at ¶¶ 95, 97; ECF 47-1. The Morgantown Form 483 focused on problematic laboratory controls and documentation practices, including the practice of impermissibly "testing into compliance." ECF 39, ¶ 97; ECF 47-1. In a separate letter, not a Warning Letter, the FDA informed Mylan that the inspections "raised questions regarding the integrity and reliability of data generated" by Mylan's quality control functions. ECF 39, ¶ 145. As a result, the FDA classified the Morgantown facility as "Voluntary Action Indicated." *Id.* at ¶ 152.

In March and April 2018, the FDA conducted another inspection of Morgantown. *Id.* at ¶ 164. Following that inspection, on April 12, 2018, the FDA issued another Form 483 for Morgantown. *Id.*; ECF 47-2. This Form 483 focused on manufacturing operations, including the processes and procedures for cleaning manufacturing equipment and utensils. ECF 47-2, pp. 2-13, 18-25.

On May 3, 2018, Mylan submitted a detailed response to the 2018 Form 483, and Mylan continued to engage with the FDA on proposed corrective actions to address the FDA's observations. ECF 47-8.

Even so, on November 9, 2018, the FDA issued a Warning Letter to Mylan about Morgantown, which "summarize[d] significant violation of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals" that had been laid out in the April 2018 Form 483. ECF 39, ¶¶ 195-206. It added that Mylan "lack[ed] an adequate ongoing program for monitoring process control to ensure stable manufacture operations and consistent drug quality." *Id.* at ¶¶ 199, 281, 283.

IV. Mylan's response to Morgantown inspection and correspondence from the FDA.

Mylan acted in response to the Warning Letter. It halted production at Morgantown while it sought to remediate the noticed violations (ECF 39, ¶ 178); it dramatically reduced the facility's production volume (*id.*); it implemented remedial measures under consultant supervision and ensured that those measures were validated and scalable before resuming production (*id.*); and it recalled at least seven drugs manufactured at Morgantown (*id.* at ¶ 180).

Publicly, as early as April 20, 2018, Mylan announced that it was "right-sizing" the Morgantown plant to make it "less complex." *Id.* at ¶¶ 11, 179, 290. At the time, Mylan explained that the rightsizing tracked discussions it was having with the FDA. *Id.*

In June 2018, Mylan acknowledged receipt of the 2018 Form 483 and stated that it had "submitted a comprehensive response to the [FDA] and committed to a robust improvement plan." ECF 39, ¶¶ 181, 184-85; ECF 47-29.

In August 2018, Mylan publicly disclosed that the restructuring and remediation program at Morgantown would include the discontinuation of several products, that the program had harmed operations (*e.g.*, it had lowered production levels and increased expenses), and that it would continue to have a negative impact through the end of 2018. ECF 39, ¶ 186; ECF 47-26, p. 3.

In November 2018, Mylan updated investors again—this time stating that the remediation program would continue into 2019 and that expenses related to these additional restructuring activities could not reasonably be estimated. ECF 39, ¶ 194; ECF 47-22; ECF 47-31.

On January 31, 2019, *Bloomberg Law* published an article in which Mylan's spokeswoman responded to allegations of CGMP and data integrity failure at Mylan's plants by stating that "[a]ny explicit or implicit suggestion that Mylan employees circumvented data and quality systems that jeopardized the quality of the medications we manufacture—for time pressures or any other reason—is simply false." ECF 39, ¶ 299.

V. Changes in Mylan's share price.

According to the amended complaint, the "relevant truth" about the FDA's inspections and Mylan's data integrity failures only began to partially surface in 2018. For example, on June 27, 2018, *Bloomberg* reported that the FDA inspected Morgantown in 2018 and issued a Form 483 listing 13 significant deficiencies in Morgantown's operations. ECF 39, ¶ 181. Soon after, Mylan's share price fell about 4%, from $37.45 per share to $36.33 per share. *Id.* at ¶ 183.

During Mylan's first earnings call after the article, Defendant Malik described the issues as "temporary" and claimed that Mylan's restructuring efforts had been planned before receiving the Form 483. *Id.* at ¶ 187. Mr. Malik tried to assuage investors that Mylan would "re-bring volume back up" following remediation of the issues observed by the FDA. *Id.* at ¶ 187. After this news, Mylan's stock price fell around 7% from $39.23 per share to $36.61 per share. *Id.* at ¶ 188.

On February 26, 2019, Mylan released its financial results for the fourth quarter of 2018. These results disclosed a 5% decline of total quarterly revenues, a 16% decline for the quarter in North American segment net sales, the discontinuation of 250 products, and $258 million in remediation costs. *Id.* at ¶¶ 207-11. In response

to this report, Mr. Malik assured investors that the negative impact from the Morgantown remediation was "largely behind" Mylan. *Id.* at ¶ 213. Once again, Mylan's stock price fell—this time $4.61 per share—but analysts were encouraged by Mr. Malik's assurance that the worst was over. *Id.* at ¶¶ 212-16.

On May 7, 2019, Mylan reported a loss for the first quarter of 2019. *Id.* at ¶ 217. After this news, Mylan's share price fell another $6.73 per share. *Id.* at ¶ 219.

VI. Plaintiff files suit.

From these core facts, Plaintiff sued Mylan, along with Ms. Bresch, its CEO, Mr. Malik, its President, and Mr. Parks, its CFO, alleging claims under Sections 10(b) and 20(a) of the Exchange Act. ECF 39. Defendants then moved to dismiss the claims in their entirety. ECF 45.

TIMELINE OF KEY EVENTS

Date	Event
Feb. 16, 2016	Beginning of class period
Sept. 5, 2016	FDA conducts surprise inspection of Nashik, India facility
Sept. 2016	FDA issues Form 483 to Mylan outlining observations from Nashik inspection
Nov. 7, 2016	FDA conducts inspection of Morgantown, West Virginia facility
Nov. 18, 2016	FDA issues Form 483 to Mylan outlining observations from Morgantown inspection
Nov. or Dec. 2016	FDA writes private letter to Mylan demanding answers for issues outlined in Form 483
Jan. 2017	Mylan privately responds to FDA letter
Apr. 3, 2017	FDA issues Warning Letter to Mylan concerning Nashik facility
Apr. 2017	Mylan executives meet in person with FDA officials
Mar. 19, 2018	FDA conducts another surprise inspection of Morgantown facility
Apr. 12, 2018	FDA issues Form 483 re: second Morgantown inspection
Apr. 20, 2018	Mylan announces that it is laying off 15% of the employees at Morgantown
May 2018	Mylan recalls several drugs manufactured at Morgantown
June 27, 2018	*Bloomberg* publishes report that FDA inspected Morgantown and "made 13 observations"; share price falls $1.12 (about 3%)
Aug. 8, 2018	Mr. Malik discloses that Morgantown had undertaken a remediation plan following the issuance of the Form 483; share price falls $2.62 per share (about 7%)

Nov. 9, 2018	FDA issues Warning Letter to Mylan concerning Morgantown facility
Feb. 26, 2019	Mylan releases financial results for fourth quarter of 2018 and full year of 2018; reports a decline in quarterly and yearly revenues and a decline in net sales for North American segment; explains that drops are "primarily due to lower volumes on existing products, which was primarily driven by actions associated with the restructuring and remediation activities at Morgantown plant"
May 7, 2019	Mylan reports loss for the first quarter of 2019 due, in part, to costs associated with Morgantown restructuring; Mylan's share price falls $6.73 (about 24%)
May 7, 2019	End of class period; over the course of the class period, Mylan's share price drops by over 50%

DISCUSSION & ANALYSIS

I. The Court will consider Plaintiff's allegations based on former employees and media sources.

Before the Court can begin to analyze the sufficiency of Plaintiff's claims, it must first establish the rules of engagement. That's because Defendants argue that the Court should disregard huge swaths of the amended complaint that are based on (1) statements from "low-level former employees" and (2) "other unnamed sources borrowed from *Bottle of Lies: The Inside Story of the Generic Drug Boom* and two articles from *Bloomberg*." ECF 46, p. 12. After careful consideration, the Court will credit these allegations in its analysis.

A. The Court will consider the statements from the former employees.

"[T]he PSLRA imposes a particularity requirement on all allegations, whether they are offered in support of a statement's falsity or of a defendant's scienter." *Institutional Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 263 (3d Cir. 2009) (citation omitted). "Thus, when considering allegations from confidential sources, the Third Circuit instructs that courts apply the particularity requirement by evaluating the detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including

from other sources, the coherence and plausibility of the allegations, and similar indicia." *In re Aurora Cannabis, Inc. Sec. Litig.*, No. 19-20588, 2022 WL 4446125, at *6 (D.N.J. Sept. 23, 2022) (cleaned up).

The crucial aspect of this evaluation is whether the confidential witnesses "are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *Wu v. GSX Techedu Inc.*, No. 20-4457, 2023 WL 2207422, at *5 (D.N.J. Feb. 24, 2023) (citing *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 244 (3d Cir. 2013)). Courts typically find sufficient particularity where the plaintiff has alleged "(1) the time period that the confidential source worked at the defendant-company, (2) the dates on which the relevant information was acquired, and (3) the facts detailing how the source obtained access to the information." *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 290 (D.N.J. 2007) (citing *Chubb*, 394 F.3d at 147) (other citations omitted)).

Defendants maintain that the allegations made by the former employees "fail to satisfy the Third Circuit's rigorous pleading requirements" and should not be credited, either to "establish falsity or [to] support an inference of scienter." ECF 46, p. 13. Defendants' position centers on two main arguments, neither of which is convincing.

First, Defendants argue that Plaintiff has failed to provide enough detail about the tenure, position, and responsibilities of the former employees to provide the Court with the necessary detail to conclude that they plausibly possessed the information alleged. The Court disagrees. The amended complaint provides the following information about the tenure and job titles of all the former employees:

FE	Tenure	Job Title
1	Entire class period (ECF 39, ¶ 95)	Quality Control and Technical Area Lead in Packaging at Morgantown (*id.*)
2	Before class period until April 2018 (*id.* at ¶ 111)	Quality Assurance Specialist at Morgantown (*id.*)
3	2016 to 2019 (*id.* at ¶ 112)	Chemist (*id.*)
4	Start of class period until mid-2016 (*id.* at ¶ 113)	Quality Control Chemist at Morgantown (*id.*)
5	Start of class period until November 2016 (*id.* at ¶ 115)	Quality Compliance Manager (*id.* at ¶ 115)
6	Before class period until Spring 2018 (*id.* at ¶ 131)	Lead Financial Analyst (*id.*)
7	Before class period until November 2018 (*id.* at ¶ 143)	Quality Assurance Supervisor (*id.*)
8	2016 to 2018 (*id.* at ¶ 160)	Technical Area Lead in Manufacturing (*id.*)

And although the descriptions of each former employee's job responsibilities vary in the degree of specificity, all are sufficient at the motion-to-dismiss stage of the case for the Court to credit the challenged allegations.

Some descriptions, like those for former employee (or "FE") 2, FE3, FE6, and FE 7, are more detailed. For example, as the Lead Financial Analysis, FE6 is alleged to have been assigned to Morgantown to help "oversee the site operations budget, with significant work on the Company's quality budget." ECF 39, ¶ 131. In that role, FE6 is said to have "supported the Vice President and Site Head of Quality at Morgantown." *Id.* Given those descriptions, the Court finds it plausible that FE6 would know details about the budget (*id.* at ¶¶ 131-35) and could offer information on the impact that the budget would have on production and compliance goals at the Morgantown facility (*id.* at ¶ 131).

The descriptions for FE2 and FE3 also provide insights into the job responsibilities of FE1, FE4, and FE5, who held similar positions. As a "Quality

Assurance Specialist" at Morgantown, FE2 was "responsible for analyzing drugs and equipment for compliance with quality standards." *Id.* at ¶ 111. FE3 worked as a chemist "responsible for quality control and validation" at Morgantown. Based on those consistent descriptions, and the job titles for and nature of the statements from FE1, FE4, and FE5, the Court infers that those former compliance-related employees had similar duties and responsibilities. And in that capacity, each of these former employees would be qualified to speak on the compliance and quality-control processes and procedures at Mylan generally, and the Morgantown facility specifically, if the former employee was alleged to have worked there during his or her tenure. *See Industriens Pensionsforsikring A/S v. Becton, Dickinson & Co.*, No. 22-2155, 2022 WL 3273879, at *11 (D.N.J. Aug. 11, 2022) ("FE-9 and FE-10's respective job title and functions further support the plausibility that they would have the information alleged. Accepting these allegations as true, as the Court must, Plaintiff has satisfactorily alleged how the FEs had access to such information." (cleaned up)).

Along with those descriptions, the mutual consistency of the former employees' accounts reinforces their reliability. They tell a story of widespread compliance and product-quality issues at Morgantown that were driven by outsized production demands imposed by management. *See, e.g.*, ECF 39, ¶¶ 108-62. They also describe that these issues were directly communicated to management and high-level executives at Mylan but not meaningfully addressed until after repeated serious warnings from the FDA. That these accounts tell the same coherent story enhances the plausibility of that story. *See Pelletier v. Endo Int'l PLC*, 439 F. Supp. 3d 450, 468 n.8 (E.D. Pa. 2020) ("[T]he [FE] allegations are specific, mutually consistent, and plausibly within the scope of knowledge each [FE] would have acquired during his or her employment[.]").

Not only that, contrary to Defendants' argument that the accounts of the

former employees are "uncorroborated by any document, meeting or witnessed discussion," they are supported by the several Forms 483 and the Warning Letter that the FDA issued to Mylan regarding the Morgantown facility. *See generally* ECF 47-1; ECF 47-2; ECF 47-3; ECF 47-6. They are further corroborated by the book *Bottle of Lies*, which is discussed below.

Considering all these allegations together, Plaintiff has set forth sufficient facts to establish the reliability of the former employees' statements, and the Court will consider them.

B. The Court will consider the allegations based on *Bottle of Lies* and the *Bloomberg* articles.

Defendants also argue that the Court should discredit Plaintiff's allegations that reference or are otherwise based on information in *Bottle of Lies* and two *Bloomberg* articles. According to Defendants, these sources are not reputable, are not particular and detailed enough to reflect their reliability, or both. The Court disagrees.

The parties agree, generally, that plaintiffs in securities actions can rely on certain media sources when making their allegations. ECF 46, p. 20; ECF 48, p. 32. Their disagreement is whether Plaintiff can rely on the specific media sources at issue. To meet the heightened pleading requirements in securities-fraud cases, "media sources must be sufficiently detailed to indicate [ ] their reliability and be based on an independent investigative effort." *In re Loewen Grp. Inc.*, No. 98-6740, 2004 WL 1853137, at *6 (E.D. Pa. Aug. 18, 2004) (cleaned up).[2] *Bottle of Lies* and the *Bloomberg* articles meet both requirements.

[2] Defendants attempt to graft on top of this standard a requirement that the media source meet some undefined and amorphous understanding of being "reputable" within the journalistic community. ECF 46, pp. 19-24. Defendants, however, cite no authority for this extra requirement, and the Court declines to impose it on Plaintiff. That said, even if the Court did adopt this extra requirement, *Bottle of Lies* and the two *Bloomberg* articles would meet it. Defendants argue that *Bottle of Lies* is "hardly

Taking *Bottle of Lies* first, author Katherine Eban's reporting is detailed enough to reflect its reliability and comes from an exhaustive independent investigative effort.

Ms. Eban, helpfully, describes her reporting process in considerable detail. As she states in her forward, the book is based on "extensive interviews, firsthand reporting, and documentation." ECF 47-33. She "interviewed over 240 people, a number of them multiple times, including regulators, drug investigators, criminal investigators, diplomats, prosecutors, scientists, lawyers, public-health experts, doctors, patients, company executives, consultants, and whistleblowers." *Id.* Her primary reporting took her to "India, China, Ghana, England, Ireland, and Mexico" and she "travel[ed] throughout the United States" to get "on-the-ground" information. *Id.* She also obtained a "significant number of confidential documents," including "20,000 internal documents from the [FDA]." *Id.* Those internal documents, in turn, contained "emails, memorandum [sic], meeting minutes, reports, and data; thousands of internal government records related to the investigation of the generic drug company Ranbaxy; and thousands of internal corporate records from several generic drug companies, including emails, reports, strategy documents, correspondence, and sealed court records." *Id.* Ms. Eban also obtained other documentation from "sixteen Freedom of Information Act requests" that she filed with the FDA, "as well as from a lawsuit that [she] filed to obtain calendar and meeting records for an FDA official."

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a well-known and reputable source" and in support cite a single critical *Washington Post* book review. ECF 46, p. 21. On the flip side, Plaintiff cites a host of favorable reviews and awards for Ms. Eban's work. ECF 48, p. 33 n.11. It is not the Court's province to wade into literary criticism and decide which opinion is the right one. The Court, instead, must focus on what Ms. Eban described as her process and decide whether that process is sufficient to yield reliable results. If so, the work is "reputable" for the purposes of the Court's analysis, regardless of any literary criticism the book may have received. As discussed in this opinion, Ms. Eban's comprehensive reporting makes *Bottle of Lies* a reputable source of information under this definition.

Id. Finally, she "read through years of publicly available FDA inspection records." *Id.*

Ms. Eban's on-the-ground reporting and firsthand review of core documents allowed her to provide insights related to several relevant topics, including, but not limited to, the 2015 and 2016 FDA whistleblower reports, Mylan's correspondence with the FDA in 2016 and 2017, and Mylan's reaction to the 2016 Form 483. ECF 39, ¶¶ 89, 91. The Court will credit this kind of effort. *See, e.g.*, *In re JPMorgan Chase & Co. Sec. Litig.*, No. 06-4675, 2007 WL 4531794, at *5 (N.D. Ill. Dec. 18, 2007) (crediting "an independent investigation" conducted by a journalist "who interviewed several individuals with personal knowledge of the merger" and provided "detail about the people involved…and the details of the negotiations, including where and when the negotiations took place, the existence of the no-premium offer, and terms of the final deal").

The same goes for the *Bloomberg* articles. Defendants do not dispute that *Bloomberg* is a "reputable" media source, because it plainly is. *See, e.g.*, ECF 47-36, p. 3 ("In a year-long investigation into FDA's regulation of the generic-drug industry, Bloomberg examined hundreds of pages of inspection documents; reviewed more than 10 years of inspection data and thousands of pages of pretrial depositions; and interviewed more than two dozen current and former FDA inspectors and agency officials, lawmakers, and industry experts."). The Court can credit articles "published in industry journals … and reputable newspapers" based on detailed reporting, like *Bloomberg's* publications, because they "meet the requirements of being independent and reliable." *Loewen Grp.*, 2004 WL 1853137, at *6.

In one last attempt to convince the Court to disregard the allegations based on *Bottle of Lies* and the *Bloomberg* articles, Defendants argue that these publications rely too heavily on "anonymous sources" that are not described with sufficient particularity to credit the information that they provide. ECF 54, pp. 21-22.

However, most of the allegations from the amended complaint that borrow from *Bottle of Lies* relate to reporting that could be plausibly corroborated by a review of documents examined by Ms. Eban and the authors of the *Bloomberg* articles. And on top of that, contrary to Defendants' suggestion, many of the unnamed witnesses are described with enough particularity to give the Court confidence that the information they provided was reliable.

For these reasons, the Court will consider the allegations in the amended complaint based on *Bottle of Lies* and the *Bloomberg* articles. *See In re Lehman Bros. Sec. & ERISA Litig.*, No. 10-6637, 2013 WL 3989066, at *4 (S.D.N.Y. July 31, 2013) (recognizing that "a plaintiff may rely in its complaint on witness statements recounted in newspaper articles" and similar sources).[3]

II. Plaintiff has alleged a material misrepresentation or omission.

With those threshold issues resolved, the Court now turns to Plaintiff's securities-fraud claim under Rule 10b-5. That rule states that it violates the Exchange Act "[t]o make any untrue statement of material fact or to omit to state a material fact … in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b-5. To state a claim under Rule 10b-5, Plaintiff must show: "(1) a material misrepresentation (or omission); (2) scienter, *i.e.*, a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance, often referred to in

[3] Defendants also suggest that Plaintiff was required to have "conducted its own investigation which corroborates the information in the article or journal." ECF 46, p. 20 (citing cases). Not so. That suggestion misreads *McKesson HBOC, Inc. Sec. Litig.*, 126 F. Supp. 2d 1248 (N.D. Cal. 2000). In *McKesson*, the court required that "the article be the result of independent investigative efforts by those authorizing or sponsoring the article." *Tracinda Corp. v. DaimlerChrysler AG*, 197 F. Supp. 2d 42, 80-81 (D. Del. 2002) (discussing *McKesson*). Counsel need not conduct a ***separate*** investigation into the article to corroborate its contents. But even if such a requirement did exist, the voluminous allegations in the amended complaint that reference witness interviews and specific documents support an inference that such an investigation was done.

cases involving public securities markets (fraud-on-the-market cases) as 'transaction causation'; (5) economic loss; and (6) 'loss causation,' *i.e.*, a causal connection between the material misrepresentation and the loss." *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 277 (3d Cir. 2010) (cleaned up). Defendants only argue at this stage that Plaintiff failed to adequately allege the first and second elements.

The first step in the Court's analysis of the Rule 10b-5 claim, then, is to determine whether Plaintiff has alleged any actionable misstatements. The heightened pleading standard of the PSLRA requires that complaints alleging securities fraud "specify each statement alleged to have been misleading" and "the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1).

"Although Rule 10b-5 imposes no duty to disclose all material, nonpublic information, once a party chooses to speak, it has a duty to be both accurate and complete." *Oklahoma Police Pension Fund & Ret. Sys. v. Teligent, Inc.*, No. 19-3354, 2020 WL 3268531, at *9 (S.D.N.Y. June 17, 2020) (cleaned up). "Disclosure is required only when necessary to make statements made, in the light of the circumstances under which they were made, not misleading." *Id.* (cleaned up).

For omitted facts to be material, "there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information available." *Id.* at 10 (cleaned up). "Because materiality is a mixed question of law and fact, a complaint may not be properly dismissed on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." *Id.* (cleaned up); *see also Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 280 n.11 (3d Cir. 1992) (citation omitted). "[A]lthough questions of materiality have traditionally been viewed as particularly appropriate for the trier of fact, complaints alleging securities fraud often contain claims of omissions or misstatements that are obviously so

unimportant that courts can rule them immaterial as a matter of law at the pleading stage." *Aetna*, 617 F.3d at 283.

Over the course of 129 pages and 354 individually numbered paragraphs, Plaintiff alleges that Defendants made many actionable misrepresentations and omissions.

For purposes of its analysis, the Court has organized the allegations of fraud into these categories: (1) statements on Mylan's public website; (2) Mylan's other self-congratulatory statements about aspects of its performance, business strategy, and compliance measures; (3) statements about Mylan's regulatory compliance; (4) statements about the "suitability" of manufacturing facilities; (5) other statements of opinion; (6) statements about "right sizing" the Morgantown facility; and (7) a statement that appears in a *Bloomberg Law* article.

After carefully reviewing the allegations, the Court finds that only the alleged misstatement or omission in paragraph 299 of the amended complaint from the *Bloomberg Law* article is actionable. Nothing else in the amended complaint can serve as the basis for Plaintiff's Rule 10b-5 claim in Count I.

A. The statements on Mylan's public website are not actionable.

Plaintiff has alleged that several statements on Mylan's website regarding the quality and reliability of its manufacturing processes were material misrepresentations. *See* ECF 39, ¶¶ 254, 256, 258, 260, 262, 264. These statements, however, cannot serve as the basis for Plaintiff's securities-fraud claim.

Rule 10b-5 states that to be actionable, an alleged misrepresentation must be made "in connection with the purchase or sale of any security[.]" 15 U.S.C. § 78j(b). This "in connection with" requirement is met "where material misrepresentations are disseminated to the public in a medium upon which a reasonable investor would rely" in deciding whether to buy or sell a security. *Rowinski v. Salomon Smith Barney Inc.*, 398 F.3d 294, 301 (3d Cir. 2005) (cleaned up). The Court must construe this

requirement "flexibly" in order to effectuate the "remedial purposes" of the statute. *SEC v. Zandford*, 535 U.S. 813, 819 (2002). But the Court must also keep in mind that the statements must "make[] a ***significant difference*** to someone's decision to purchase or sell" a security. *Chadbourne & Parke LLP v. Troice*, 571 U.S. 377, 387 (2014) (emphasis added).

After careful consideration, the Court concludes that the statements from Mylan's website are not the type of statements upon which a reasonable investor would rely.

To start, the alleged misstatements appeared on Mylan's general website, not its investor-relations page. While certainly not dispositive, this fact suggests that investors visiting Mylan's website would view the information contained on the separate investor-relations page to have more value to them, since it was specifically targeted to them. The information on the other pages within Mylan's website drives this point.

These other pages included things like descriptions of products, general statements about safety and quality, and narratives regarding the company's history. Essentially, these pages are all about promoting Mylan, its brand, and its products. "No reasonable investor would rely upon these promotional phrases in making investment decisions." *In re Medtronic Inc., Sec. Litig.*, 618 F. Supp. 2d 1016, 1030 (D. Minn. 2009) (holding that information published "about the Fidelis lead on its website to promote it to physicians" was not made in connection with the sale of securities), *aff'd sub nom. Detroit Gen. Ret. Sys. v. Medtronic, Inc.*, 621 F.3d 800 (8th Cir. 2010).[4]

[4] Unlike the defendant in *Howard v. Arconic*, No. 17-cv-1057, 2021 WL 2561895 (W.D. Pa. June 23, 2021) (Hornak, C.J.), a case cited by Plaintiff, Mylan specifically directed investors to its "Investor Relations" page, which did not include the challenged statements. *See* ECF 54, p. 12 n.13.

The nature of the statements themselves further underscores this fact. They are best characterized as statements of "corporate optimism, "mere puffing," or "generalized statements of optimism." *Grossman v. Novell, Inc.*, 120 F.3d 1112, 1119 (10th Cir. 1997). Classic examples of puffery are when a company offers "[v]ague positive statements regarding a corporate entity's risk management strategy, asset quality, and business practices[.]" *In re Synchrony Fin. Sec. Litig.*, 988 F.3d 157, 170 (2d Cir. 2021). A reasonable investor cannot rely on such statements because they are too general.

All the statements from Mylan's website fall into this category:

- "[T]here's nothing generic about our standards. Our internal teams conduct reviews of all products, start to finish." ECF 39, ¶ 254.

- "[O]ur priorities are to meet or exceed industry standards. Our own teams conduct ongoing reviews to ensure quality and integrity of products, start to finish, and to continually improve for optimal quality and consistency." *Id.* at ¶ 256.

- "Mylan uses advanced testing and monitoring systems to assure product adheres to testing acceptance criteria that are in alignment with requirements established by standard-setting organizations around the world." *Id.* at ¶ 258.

- "Mylan utilizes state-of-the-art monitoring systems that can automatically evaluate and reject a product that does not meet specifications." *Id.* at ¶ 260.

- "Mylan assures product potency, purity, and drug release through expiration date by testing the stability of our products at specific intervals." *Id.* at ¶ 262.

These general statements about Mylan's "standards" and "systems" are non-actionable because "they do no more than reflect statements that are loosely optimistic regarding [the] company's well-being, and they are so vague, broad, and non-specific that a reasonable investor would not rely on them." *In re AstraZeneca*

PLC Sec. Litig., No. 21-722, 2022 WL 4133258, at *8 (S.D.N.Y. 2022) (cleaned up; collecting cases). That's especially true here since Mylan was simultaneously publicly disclosing the significant regulatory risks facing the company in all its SEC filings. A reasonable investor would therefore recognize that while Mylan might subjectively believe that it uses "advanced" and "state-of-the-art" systems and that its standards were not "generic," it was possible regulators might not agree. *See In re Peabody Energy Corp. Sec. Litig.*, No. 20-8024, 2022 WL 671222, at *13-14 (S.D.N.Y. Mar. 7, 2022).

The allegations based on statements from Mylan's public website do not state a claim.

B. Mylan's other self-congratulatory statements about aspects of its performance, business strategy, and compliance measures are not actionable.

The same "puffery" analysis discussed in the previous section applies with equal force to various soft statements cited in the amended complaint. This is all puffery—Mylan describing: (1) its overall "operational excellence" (ECF 39, ¶ 271), (2) its "deep and unwavering commitment to quality" (*id.* at ¶ 279), (3) its manufacturing platform as "[p]owerful" and "high quality" (*id.* at ¶ 281), (4) its quality standards as "stringent" (*id.* at ¶ 283), (5) its investments in "quality" (*id.* at ¶¶ 284, 292-93), (6) its business strategy as "win-win" (*id.* at ¶ 303), (7) its manufacturing operations as "extensive" (*id.* at ¶ 304), and (8) its supply chain as "reliable" and "second to none" (*id.* at ¶¶ 305-07). *See, e.g.*, *Aetna*, 617 F.3d at 280 n.7, 283-84 (dismissing claims where underwriting and pricing practices were described as "strong," "disciplined," and "rigor[ous]"); *SEPTA v. Orrstown Fin. Servs., Inc.*, No. 12-993, 2015 WL 3833849, at *19 (M.D. Pa. June 22, 2015) (finding that "representations of … 'stringent' underwriting standards are … accurately characterized as puffery, or a positive portrayal so vague as to be immaterial to a

reasonable investor."); *Freedman v. St. Jude Med., Inc.*, 4 F. Supp. 3d 1101, 1107-13 (D. Minn. 2014) (finding "strict design rules" and "high quality product designs" immaterial despite Forms 483 citing design deficiencies). These adjective-laden statements are too vague to be verified. What makes a manufacturing platform "powerful"? What constitutes "operational excellence"? A reasonable investor would not put stock in these corporate platitudes.

Similarly, these statements too are all puffery: Mylan's statements about (1) its "commitment" to "maintaining the highest quality manufacturing standards at its facilities around the world" (ECF 39, ¶ 297), (2) being "best positioned to take [its] entire product portfolio across the globe" (*id.* at ¶ 310), (3) its ability to "leverage" its platform and portfolio (*id.* at ¶¶ 311-12), and (4) "celebrating" or expressing "excitement" about "the credibility of [Mylan's] science, our portfolio, our ability, our operational excellence, the ability to manufacture high-quality, high-volume products around the globe" (*id.* at ¶¶ 317, 319). *See, e.g.*, *Advanta*, 180 F.3d at 537-38 (statements puffery where cost structure, credit quality, and customer recruiting process described as "superior," "excellent" and "high quality"); *In re Hertz Glob. Holdings, Inc. Sec. Litig.*, No. 13-7050, 2017 WL 1536223, at *10-11 (D.N.J. Apr. 27, 2017) ("sustained operational excellence" statement was immaterial because it was not "determina[ble]" or "verifiable"), *aff'd sub nom. In re Hertz Glob. Holdings Inc*, 905 F.3d 106 (3d Cir. 2018); *In re AstraZeneca*, 2022 WL 4133258, at *8 (finding that statements about "various commitments to public safety and equitable access" could not support a claim "even if the statements are in tension with any omissions in some abstract sense"). These aspirational statements "read like mission statements rather than guarantees" in that they outline goals toward which Mylan is working, rather than listing objective accomplishments. *Howard v. Arconic Inc.*, 395 F. Supp. 3d 516, 547 (W.D. Pa. 2019) (Hornak, C.J.); *see, e.g.*, ECF 39, ¶ 284 (Mylan conducting a

"series of reviews ***designed to*** meet or exceed…regulatory…standards…around the globe" (emphasis added)).

C. Statements about Mylan's regulatory compliance are not actionable.

Plaintiff next alleges that Defendants misled investors about the status of Mylan's regulatory compliance in several of Mylan's SEC filings during the class period. Specifically, Plaintiff claims that it was misleading for Mylan to suggest that "there is no guarantee" that its compliance programs and policies "will meet regulatory agency standards in the future or will prevent instances of non-compliance with applicable laws and regulations," and that Mylan only "may receive" notices of regulatory violations in the future. ECF 39, ¶¶ 269, 275, 289, 296. According to Plaintiff, these statements were misleading because they only stated that compliance-related risks might occur in the future, when, in fact, Mylan had already received notices of significant violations. *Id.* at ¶¶ 270, 276, 289, 296. Plaintiff's claim fails, ironically, because of what it selectively omitted from its quotation of the at-issue SEC filings.

In the amended complaint, Plaintiff left out this important bit of adjacent information from the SEC disclosure:

> [D]espite our efforts at compliance, from time to time we receive notices of manufacturing and quality-related observations following inspections by regulatory authorities around the world, as well as official agency correspondence regarding compliance. We may receive similar observations and correspondence in the future.

See, e.g., ECF 47-20, p. 36. Adding in the unedited "context of the complained-of statements…actually cuts [Plaintiff's] argument out from under it." *Carvelli v. Ocwen Fin. Corp.*, 934 F.3d 1307, 1322 (11th Cir. 2019). That's because Plaintiff's omission demonstrates that Mylan disclosed the very thing that Plaintiff claims was left out—that Mylan had already received "quality-related observations following inspections by regulatory authorities." *In re Lions Gate Entm't Corp. Sec. Litig.*, 165

F. Supp. 3d 1, 15-16 (S.D.N.Y. 2016) (finding that there was "nothing false or misleading" about repeated statements in SEC filings that "[f]rom time to time, the Company is involved in certain claims and legal proceeding arising in the normal course of business" because "they accurately describe that there were currently pending claims or legal proceedings").

The added context of the other risk disclosures in these same SEC filings further undermines Plaintiff's position. In each of Mylan's SEC quarterly and annual filings during the class period, Mylan included the following cautionary statements:

- THE PHARMACEUTICAL INDUSTRY IS HEAVILY REGULATED AND WE FACE SIGNIFICANT COSTS AND UNCERTAINTIES ASSOCIATED WITH OUR EFFORTS TO COMPLY WITH APPLICABLE LAWS AND REGULATIONS (ECF 47-19, pp. 33-34 (emphasis in original); *see also* ECF 47-18, pp. 22-23; ECF 47-20, pp. 35-36; ECF 47-21, pp. 33-34); and
- Although we have established internal quality and regulatory compliance programs and policies, there is no guarantee that these programs and policies, as currently designed, will meet regulatory agency standards in the future or will prevent instances of non-compliance with applicable laws and regulations (ECF 47-18, p. 23).

Mylan also advised investors of the potentially severe consequences of any non-compliance, including "receipt of an untitled or warning letter, … unanticipated compliance expenditures, … [and/or] total or partial suspension of production and/or distribution," which could materially affect Mylan's "business, financial condition, [and] results of operations[.]" ECF 47-19, p. 33; *see also* ECF 47-20, p. 36.

These added disclosures made it clear that, even under the best circumstances, there was "uncertainty as to the very possibility of adequate compliance…in light of complex and shifting government regulations." *Singh v. Cigna Corp.*, 918 F.3d 57, 64 (2d Cir. 2019). That uncertainty was even more pronounced here since Mylan was telling investors that it, in fact, had already received (and would continue to receive) notices of non-compliance. *See Garnett v. RLX Tech. Inc.*, No. 21-5125, 2022 WL

4632323, at *19 (S.D.N.Y. Sept. 30, 2022) ("Viewed as a whole, these statements in the Offering Materials fairly alerted investors to the existing regulatory strictures in China governing e-cigarettes, the prospect that heightened regulation of these products would be undertaken, and the attendant risks to investors.").

Considering what securities law refers to as the "total mix" of information available to investors, Mylan's compliance disclosures did not misleadingly "suggest that adverse consequences were only a possibility" and that the company was currently compliant despite allegedly "widespread" and "serious compliance issues." ECF 39, ¶¶ 269, 275, 289, 296. Rather, they told investors the truth: Mylan faced serious business risk because of the heavily regulated industry in which it operated, and that maintaining adequate compliance would be a significant undertaking—an undertaking at which it would sometimes come up short. Therefore, the alleged misrepresentations in paragraphs 269, 275, 289, and 296 of the amended complaint cannot serve as the basis for Plaintiff's Rule 10b-5 claim.

D. Mylan's opinion statements about the "suitability" of its manufacturing facilities are not actionable.

Plaintiff also challenges Mylan's repeated statement about the "suitability" of its manufacturing facilities:

> We believe that all of our facilities are in good operating condition, the machinery and equipment are well-maintained, the facilities are suitable for their intended purposes and they have capacities adequate for the current operations.

See ECF 39, ¶¶ 267, 273, 288. Plaintiff alleges that this statement was misleading because Mylan's facilities "were rife with serious, repeat CGMP and data integrity violations." *Id.* at ¶ 268. The Court, though, does not find this statement to be actionable.

Mylan's statement, with its "we believe" language, is clearly an opinion. *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175,

183-84 (2015) (words like "I think" or "I believe" connote opinions). Of course, an opinion can be "misleading if it omits material facts about the inquiry into or knowledge concerning a statement of opinion." *Jaroslawicz v. M&T Bank Corp.*, 962 F.3d 701, 717 (3d Cir. 2020) (cleaned up). "But liability attaches only if those facts conflict with what a reasonable investor would take from the statement itself." *Id.* (cleaned up). Thus, alleging an actionable opinion "is no small task" because "a reasonable investor understands that opinions sometimes rest on a weighing of competing facts; indeed, the presence of such facts is one reason why an issuer may frame a statement as an opinion." *Id.* (cleaned up).

Plaintiff's allegations do not meet this "rigorous benchmark." *Id.* The facts that Plaintiff alleges were omitted don't even relate to the content of the statement at issue. That statement speaks to whether Mylan's facilities had the necessary operational equipment to allow for manufacturing at the levels required for its business. In other words, this statement is clearly and objectively about the physical condition of the manufacturing facilities and the machinery and equipment contained within them. It does not go to whether those facilities complied with all the regulatory requirements related to quality control testing, data integrity, or cleaning that was the focus of the FDA's observations and warnings. Because there is no allegation that Mylan offered an insincere opinion about the physical characteristics of its manufacturing facilities, any claim based on these "suitability" statements fails. *See, e.g.*, *Omnicare*, 575 U.S. at 194 (plaintiff must "identify particular (and material) facts" that "call into question the issuer's basis for offering the opinion."); *PolarityTE*, 2020 WL 6873798, at *10 ("there is no plausible basis to think…the Form [483] somehow alters the meaning of the statement" describing manufacturing facilities layout and capabilities).

E. Mylan's other statements of opinion are not actionable.

Similarly, the amended complaint does not state a claim based on allegations

that Defendants' positive opinions about Mylan's business strategy or outlook during the class period were misleading.

The challenged statements in this category outline Mylan's decision not to reduce its product portfolio in the hope that its reputation as a reliable supplier would put the company in a good position to gain market share as competitors exited certain segments of the market. *See, e.g.*, ECF 39, ¶ 302 (Bresch: "our ability to be nimble, to react to market opportunities, to react to customer disruption…certainly then puts a different perspective of how you're leveraged with the customers"); ¶ 305 (Bresch: "I think" that the "need for a reliable supply" will "be a differentiator" and "a real value driver and growth driver for us"); ¶ 307 (Bresch: "I truly think" that "ability to be that reliable supplier" will allow for "capacity to do the kind of the [sic] volumes that need to be done"); ¶ 313 (Bresch: "I think, where Mylan has differentiated itself is, one, having that broad base, that portfolio, the capacity to truly meet the supply that's needed[.]"); ¶ 314 (Bresch: "I think we have found ourselves in a position" to maintain production levels for generics); ¶ 315 (Bresch: "I think" that as other "companies are rationalizing" Mylan is "able to kind of be patient"); ¶ 316 (Parks: "I think some of these larger customers value the fact that you can bring to them more today than 5 years ago the ability to supply them with a broader range of products"). Plaintiff alleges that these statements were misleading because Defendants did not disclose that Mylan was quietly compromising quality to meet volume demands. ECF 48, p. 38. The Court disagrees.

Defendants did not base their belief that Mylan could gain market share on the ***quality*** of its manufacturing processes, but instead based it on Mylan's "ability to provide all the different products [its customers] need[ed]." ECF 39, ¶¶ 303, 308, 309, 312, 315. On that score, Plaintiff does not allege that Defendants did not genuinely believe that Mylan possessed the ability to produce a diverse portfolio of products in volumes that would provide a competitive advantage; only that

compromising quality (and the attendant regulatory risks that would come with such a compromise) could jeopardize Mylan's rosy outlook. Plaintiff's argument "essentially boils down to an allegation that the statements were misleading for failure to include a fact that would have potentially undermined Defendants' optimistic projections." *Tongue v. Sanofi*, 816 F.3d 199, 212 (2d Cir. 2016).

The problem with that argument is that when expressing an optimistic opinion about Mylan's future, Defendants didn't have to disclose every possible problem that could arise along the way. *Omnicare*, 575 U.S. at 194 ("[a]n opinion statement … is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way"). Rather, such an obligation could only arise if the undisclosed fact made it impossible for the speaker's opinion to be correct. But the individual Defendants' alleged knowledge of systemic quality and data integrity issues would not mean that "it was *impossible*" for Mylan to execute its business strategy. *Carvelli v. Ocwen Fin. Corp.*, 934 F.3d 1307, 1329 n.13 (11th Cir. 2019) (emphasis in original).

This is true even where, as Plaintiff alleges, some of the individual Defendants' knowledge came from asserted violations on the Forms 483. Importantly, a Form 483 is simply "interim FDA feedback." *Schaeffer v. Nabriva Therapeutics PLC*, No. 19-4813, 2020 WL 7701463, at *9 (S.D.N.Y. Apr. 28, 2020). The "advisory language that accompanies all Forms 483" makes clear that the forms "do not represent the FDA's final word" and "do not represent a final agency determination regarding…compliance." *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 35 (1st Cir. 2014) (cleaned up). Consequently, Mylan, as it did here, had the opportunity to address that feedback, while continuing its operations. Any quality and data integrity issues might have made it tougher for Mylan to meet its production goals if the problems could not be adequately resolved, but they wouldn't have made it impossible.

In the end, "Plaintiff may disagree with Defendants' opinion, but so long as Defendants conducted a meaningful inquiry and in fact held the stated view, the statements did not mislead in a manner that is actionable." *In re Investment Tech. Grp., Inc. Sec. Litig.*, 251 F. Supp. 3d 596, 619 (S.D.N.Y. 2017) (cleaned up). The Court finds that these opinion statements about Mylan's business strategy and outlook are not actionable.

F. Statements about "right sizing" the Morgantown facility were not materially misleading.

Plaintiff next argues that "Defendants made false and misleading statements about the expansive remediation that was undertaken at Morgantown." ECF 48, p. 41. According to Plaintiff, Defendants "downplayed the Morgantown issues" by claiming that a "compelled remediation" was part of an existing plan to "right size" the facility and that any disruption would be "temporary." *Id.* at p. 42. After carefully reviewing the statements that serve as the crux for this claim, the Court finds that the statements were not misleading because they did not downplay anything—they, in fact, painted a grim picture of the circumstances at Morgantown.[5] *See, e.g.*, ECF 39, ¶¶ 290, 321-23, 325.

[5] They are also, explicitly, forward-looking statements. ECF 47-31, p. 4 ("During today's call, we will be making forward-looking statements on a number of matters" that are "subject to risks and uncertainties that could cause future results or events to differ materially from today's projections."); ECF 47-32, p.4 (same). Forward-looking statements are protected if they are "either accompanied by 'substantive and tailored' cautionary statements or if the plaintiff fails to show actual knowledge of falsehood." *OFI Asset Mgmt. v. Cooper Tire & Rubber*, 834 F.3d 481, 491 (3d Cir. 2016) (cleaned up). The statements here are protected under both prongs. There were substantive and tailored cautionary statements made contemporaneously with the earnings calls about the "risks and uncertainties" regarding the predictions made by senior management, including the fact that Mylan might be "unable to achieve expected synergies and operating efficiencies in connection with … restructuring programs within the expected time-frames or at all." ECF 47-26, p. 10. Plaintiff also does not allege sufficient facts to establish that the individual Defendants who spoke on these earnings calls knew their statements were false at the time they were made.

Most of these statements were made during two earnings calls. During the first call, Mr. Malik discussed the FDA inspection at Morgantown and the observations in the Form 483. ECF 47-32, pp. 6-7. He then said in the next breath that Mylan had "undertaken a restructuring and remediation program," which included "a discontinuation of a number of products" to "reduc[e] complexity." *Id.* at p. 7. Those actions led to a "negative impact on production levels, product supply and operations." *Id.* In response to investor questions, Mr. Malik and Ms. Bresch would only say that Mylan was "hopeful" that it would "be able to rebring volume back up" by the end of the year. *Id.* at p. 9. But that hope was tempered by the reality that it would be "difficult for [Mylan] to manage [the] sort of complexity which Morgantown [had]." *Id.* Importantly, Mr. Malik never denied that this program was put in place because of the FDA's observations. *Id.* Later on, Mr. Parks disclosed that the program had cost the company $87 million. *Id.* at p. 7.

The outlook didn't get any rosier during the second call a few months later. Mr. Malik noted that Mylan was still working to "reduce the complexity" of the Morgantown facility and reiterated that the company had "discontinued a number of products while also transferring some to other sites." ECF 47-31, p. 5. He stated again that these actions led to a "disruption" of the "supply of certain products for [Mylan's] customers and reduced volume in North America generic sales." *Id.* He also made clear that the "remediation and restructuring activities" would "continue in the near term." *Id.* at p. 6. Mr. Parks then updated investors that the costs of restructuring and remediation had materially increased to $98 million. *Id.*

Taking these two earnings calls together, Mylan was being forthright about the challenges facing the Morgantown facility. There was no definitive end in sight for the restructuring and remediation program and only "hope" that production volumes would match previous levels in the near term.

Mylan painted an even bleaker picture in its contemporaneous SEC filings. In its 8-K filed on the same day as the first earnings call, Mylan stated that its restructuring and remediation program at Morgantown had "a ***significantly negative impact*** on production levels, product supply and operations." ECF 47-26, p. 3 (emphasis added). Similar statements were repeated in the 8-K filed on the same day as the second call. ECF 47-25, p. 2 ("[remediation] program includes the discontinuation and transfer to other manufacturing sites of a number of products, a reduction of the workforce and extensive remediation activities. These actions have led to a temporary disruption in supply of certain products."). Mylan further stated that it "expected" its "remediation activities, lower production levels, [and] the negative impact on operations and related expenses to ***continue through the end of 2018***." ECF 47-26, p. 3 (emphasis added). The added context of these SEC filings makes it even clearer that Defendants did not mislead investors about the state of the remediation and restricting activities during the at-issue conference calls.

In sum, Defendants' statements during the earnings calls cannot be actionable omissions because they disclosed the exact information that Plaintiff alleges was concealed to the market (*i.e.,* that the remediation efforts triggered, in part, by the FDA's inspections and observations significantly affected Morgantown's productivity). *See Anderson v. StoneMor Partners, L.P.*, 296 F. Supp. 3d 693, 703 (E.D. Pa. 2017) (dismissing claim where defendant "disclosed the very information Plaintiffs allege was concealed from the market"), *aff'd sub nom. Fan v. StoneMor Partners, L.P.*, 927 F.3d 710 (3d Cir. 2019); *Shemian v. Research In Motion Ltd.*, No. 11-4068, 2013 WL 1285779, at *20 (S.D.N.Y. Mar. 29, 2013) (dismissing claim based on alleged omission where information at issue was in fact disclosed), *aff'd*, 570 F. App'x 32 (2d Cir. 2014).[6]

[6] The same is true about Mylan's allegedly misleading statement in its Form 10-Q on May 10, 2018, that there had been no material changes in the company's risk factors.

G. Mylan's declaration in the *Bloomberg Law* article is actionable.

That leaves one final statement that has not been addressed elsewhere in this opinion. That statement appeared in an article in *Bloomberg Law* on January 31, 2019. ECF 39, ¶ 299. In that article, a Mylan spokeswoman, Lauren Kashtan, responded to allegations of CGMP and data integrity failures at Mylan's plants by declaring that "[a]ny explicit or implicit suggestion that Mylan employees circumvented data and quality systems that jeopardized the quality of the medications we manufacture—for time pressures or any other reason—is simply false." ECF 47-37, p. 6. Unlike the other statements that Mylan made, this one is actionable.

Ms. Kashtan's statement on behalf of Mylan wasn't corporate puffery or a statement of her opinion. It wasn't qualified. It wasn't aspirational. It was a declaration that, at that moment in time, any "suggestion" that Mylan employees circumvented "data and quality systems that jeopardized the quality of the medications" it manufactured was "simply false." The amended complaint alleges in detail—largely through accounts of former employees—the clear circumvention of quality controls at Mylan to cut corners for time pressure and in a way that jeopardized the quality of the medications. ECF 39, ¶¶ 108-77. The Court therefore finds that this statement by Mylan, which was published in the January 2019 *Bloomberg Law*, was a material misrepresentation and can serve as the basis for Plaintiff's Rule 10b-5 claim.

III. Plaintiff has adequately alleged corporate scienter.

Having found one alleged material misrepresentation, the Court must now turn to the second step of its analysis—determining whether Plaintiff has adequately

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ECF 39, ¶ 295. That statement is talking about the regulatory risk from a macro perspective, and those risks had not changed. And that also goes for Mr. Malik's statement during an earnings call in 2017 about the FDA warning letter at the Nashik site, which is quoted in paragraph 286 of the amended complaint.

alleged scienter as it relates to that statement.

"Scienter is a mental state embracing intent to deceive, manipulate, or defraud." *Institutional Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009) (cleaned up). A plaintiff alleging scienter must assert facts giving rise to a strong inference of reckless or conscious behavior. *Martin v. GNC Holdings, Inc.*, 757 F. App'x 151, 153-54 (3d Cir. 2018) (citation omitted). "A reckless statement is one involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Avaya*, 564 F.3d at 267 n.42 (citation omitted).

To determine whether the allegations in the amended complaint satisfy the scienter requirement, the Court must engage in a three-part analysis.

First, the Court accepts "all factual allegations in the complaint as true." *Martin*, 757 F. App'x at 154 (citation omitted).

Second, the Court determines "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Id.* (cleaned up); *see also OFI Asset Mgmt.*, 834 F.3d at 493 (noting that the court must "consider[] all the arguments presented by the Complaint and assess[] scienter holistically"). Such an inference can arise where the defendants "knew facts or had access to information suggesting that their public statements were not accurate ... or ... failed to check information they had a duty to monitor." *Plumbers & Steamfitters Local 773 Pension Fund v. Canadian Imperial Bank of Commerce*, 694 F. Supp. 2d 287, 298 (S.D.N.Y. 2010) (citation omitted).

Third, "to determine whether the allegations give rise to a 'strong' inference of scienter, [the Court] take[s] into account plausible opposing inferences." Martin, 757

F. App'x. at 154 (cleaned up). In other words, on this last part, the Court "must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Id.* (cleaned up). "A securities fraud complaint will therefore only survive a 12(b)(6) motion to dismiss if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* (cleaned up).

To begin with, Plaintiff cannot establish scienter as to the *Bloomberg Law* statement with respect to the three individual Defendants. There are no allegations in the amended complaint as to their role in drafting, reviewing, or approving the statement. Therefore, Count I of the amended complaint as against the individual Defendants will be dismissed. *Allegheny Cnty. Emps.' Ret. Sys. v. Energy Transfer LP*, 532 F. Supp. 3d 189, 232 (E.D. Pa. 2021) ("[A] person with ultimate authority over a statement can be liable under Rule 10b-5, even without uttering the words of the statement. But Plaintiffs have not alleged with particularity facts showing that McGinn or Hennigan had ultimate authority for any of the statements at issue.").[7]

[7] Any effort to attribute the statement in the January 2019 *Bloomberg* article to the individual Defendants fails "because it represents impermissible group-pleading." *Energy Transfer*, 532 F. Supp. 3d at 235. "Group-pleading is a judicial presumption that statements in group-published documents are attributable to officers in that group." *Id.* (cleaned up). When group-pleading is permitted, it allows a "plaintiff to plead that defendants made a misstatement or omission of a material fact without pleading particular facts associating the defendants to the alleged fraud." *Winer Family Tr. v. Queen*, 503 F.3d 319, 335 (3d Cir. 2007). The Third Circuit, though, has rejected group-pleading as inconsistent with the heightened pleading standards of the PSLRA. *Id.* at 336-37. In *Winer*, the Third Circuit found an effort to connect unattributed statements to the corporation by pleading that the individual Defendants had "access to, control over, and ability to edit and withhold dissemination of [the corporation's] press releases and SEC filings" was insufficient. *Id.* at 334-35. To attribute the statements from the *Bloomberg Law* article to any of the individual Defendants, Plaintiff would have to make this same (already rejected) argument.

But the Court finds that Plaintiff has adequately pled "corporate scienter," and so the claim against Mylan may proceed. "Courts are divided on whether and when scienter is adequately alleged as to a corporation in the absence of scienter allegations as to the individual who made the material misstatement." *In re Cognizant Tech. Sols. Corp. Sec. Litig.*, No. 16-6509, 2018 WL 3772675, at *31 (D.N.J. Aug. 8, 2018). And the Third Circuit has not squarely decided the issue.[8] *Id.* at *32 (cleaned up).

On the facts alleged here, the concept of corporate scienter seems particularly applicable. The unattributed statements contained in the *Bloomberg Law* article "are all statements made *ex cathedra*, on behalf of the corporation," and "there is ample evidence that high-ranking corporate officials were personally engaged in the details of the project, making it highly unlikely that the unattributed statements were rogue pronouncements by employees lacking authority to speak on the corporation's behalf." *Energy Transfer*, 532 F. Supp. 3d at 237. And then there is the nature of that statement. It was a statement of then-existing fact that Mylan's senior management team allegedly knew was false (or at least materially misleading) given the corporation's recent history of compliance issues at several of its flagship manufacturing facilities.

There are three approaches to corporate scienter the Court could adopt: broad, intermediate, and narrow. First, the broad approach. "Some courts, including the Second and Seventh Circuits, have adopted a [broad] theory of 'collective' or 'corporate' scienter and held that allegations can give rise to a strong inference of scienter as to the corporation even if they do not give rise to an inference of scienter

[8] "We, however, neither have accepted nor rejected the doctrine of corporate scienter in securities fraud actions, and we do not do so now[.]" *Rahman*, 736 F.3d at 246; *see also In re Hertz Global Holdings, Inc.*, 905 F.3d 106, 121 n.6 (3d Cir. 2018) ("We have neither accepted nor rejected that doctrine and decline to do so here because the … allegations would not give rise to corporate scienter under any recognized theory of that doctrine." (citation omitted)).

as to the individual who uttered the material misstatement." *In re Cognizant*, 2018 WL 3772675, at *31 (cleaned up).[9]

In contrast, courts adopting the narrow approach "require a strong inference of scienter as to the individual corporate official or officials who make or issue the statement rather than generally to the collective knowledge of all the corporation's officers and employees." *Id.* (citing cases from the Fifth and Eleventh Circuits).

And finally, the Sixth Circuit has carved out a middle ground or intermediate approach, in which the court considers the mental state of "[t]he individual agent who uttered or issued the misrepresentation; … [a]ny individual agent who authorized, requested, commanded, furnished information for, prepared…, reviewed, or approved the statement…; [and] … [a]ny high managerial agent or member of the board of directors who ratified, recklessly disregarded, or tolerated the misrepresentation after its utterance or issuance." *In re Omnicare, Inc. Sec. Litig.*, 769 F.3d 455, 476 (6th Cir. 2014).

Like the other district courts from this Circuit that have waded into these waters, this Court declines to adopt the narrow approach. *See In re Cognizant*, 2018 WL 3772675, at *33; *Energy Transfer*, 532 F. Supp. 3d at 237. That approach "has a significant disadvantage: it allows corporations to evade liability through tacit encouragement and willful ignorance and fails to address instances where widespread corporate fraud cannot be connected to individual defendants at the pleading stage." *Energy Transfer*, 532 F. Supp. 3d at 237 (cleaned up). Plus, "[s]lanting too far toward" the narrow approach "risks running counter to the goals and purposes of the 1934 Act—which includes fostering an attitude of full disclosure

[9] The Ninth Circuit has also recognized that "in certain circumstances, some form of collective scienter pleading might be appropriate." *Glazer Capital Mgmt., LP v. Magistri*, 549 F.3d 736, 744 (9th Cir. 2008).

by publicly traded corporations, rather than a philosophy of *caveat emptor* for securities buyers." *Id.* (cleaned up).

Having rejected the narrow approach, the Court need not predict whether the Third Circuit would adopt the broad or intermediate approach because the allegations in the amended complaint satisfy both.

Starting with the broader approach, Plaintiff alleges in the amended complaint that there was a pervasive, top-down scheme to dupe the FDA and ignore regulatory compliance best practices in the name of juicing manufacturing output and increasing corporate profits. It was not limited to a "group of rogue employees perpetuating fraud and concealing it from corporate management, but instead was a pervasive operation extending from senior management itself." *In re Cognizant*, 2018 WL 3772675, at *33. Under these circumstances, an inference of fraud is at least as likely, if not more so, than an inference of recklessness. *See id.* at *34 ("[W]hen there is circumstantial evidence creating a strong inference that someone involved in the making of the misstatement was aware of its falsity, the 'collective scienter' theory is appropriate to allow plaintiffs to proceed to discovery.").

The Court reaches the same conclusion on scienter under the intermediate approach. The scienter of Defendants Malik, Bresch, and Parks may be imputed to Mylan because each is a "high managerial agent … who ratified, recklessly disregarded, or tolerated the misrepresentation after its utterance or issuance." *Omnicare*, 769 F.3d at 476. These individual Defendants had access to observations and warnings from the FDA that directly contradicted the company's public statement in the *Bloomberg Law* article. The clearest examples of this access are the Forms 483 and Warning Letters that Mylan received about its Nashik and Morgantown facilities.

For example, with respect to Morgantown, in March 2018, the FDA observed that the "responsibilities and procedures applicable to the quality control unit are not

fully followed." ECF 47-2, p. 1. One consequence of this failure was that "[l]aboratory analyses are repeated until passing results are obtained." *Id.* at p. 13. Many of these violations were repeat violations, as the FDA outlined in its Warning Letter dated November 9, 2018. ECF 47-6, pp. 6-7. According to the FDA, those "repeated failures at multiple sites demonstrate[d] that Mylan's management oversight and control over the manufacture of drugs [wa]s inadequate." *Id.* at p. 7. And that lack of oversight, in turn, was "a major factor in the unexpected variation observed in [Mylan's] drug products." *Id.* at p. 5. These issues were serious. As the FDA put it in its Warning Letter, Mylan's failure to correct them could lead to "legal action without further notice including, without limitation, seizure and injunction." *Id.* at p. 7. The FDA could also "withhold approval of pending drug applications" from drugs manufactured at those facilities. *Id.* The Warning Letter was addressed directly to Ms. Bresch and was sent less than a year before the *Bloomberg Law* article was published. *Id.* at p. 1. These issues were clearly fresh in the minds of senior management.

But that's not all. Even earlier, the FDA allegedly told Mylan executives, including Mr. Malik, that it was "stunned" by the "egregious" violations in the 2016 Form 483 and questioned whether Mylan was being "transparent at all of its sites." EC 39, ¶¶ 9, 150, 224. According to the former employees detailed in the amended complaint, Mr. Malik balked at implementing meaningful changes to address the violations, and instead internally demanded that Morgantown increase its annual production goals and cut its regulatory compliance and quality control budget. *Id.* at ¶¶ 8, 132, 135, 157.

These direct warnings to Mylan's senior management support a strong inference of their scienter, which can, in turn, be imputed to Mylan. *See Able Labs*, 2008 WL 1967509, at *16-17 (finding scienter where: (i) Form 483 and warning letter "provided notice to the defendants that serious problems existed in the [company's] manufacturing process"; (ii) the president's "receipt and review of the FDA warning

letter should have alerted him to potential problems"; and (iii) the "FDA investigation and Form 483 demonstrate that numerous problems with … quality controls continued" after receiving initial warnings).

The last step in the scienter analysis requires the Court to examine any non-culpable competing inferences. On this issue, Defendants argue that "there are numerous non-culpable and far more compelling explanations as to why Mylan did [] or did not immediately disclose the Form[s] 483," including that Forms 483 "are non-final; it was reasonable to wait to disclose until the FDA's concerns and proposed remediations crystalized; Defendants reasonably believed the FDA's concerns could be remedied; and investors were repeatedly warned that compliance was not guaranteed and that Form[s 483] were received from time to time." ECF 54, p. 26 (cleaned up).

But none of those proffered "compelling explanations" really apply to the statement in the *Bloomberg Law* article. At that point, the FDA's concerns had been repeatedly clarified. And while Mylan may have believed it could remedy those concerns, claiming that any "suggestion" of compliance issues was objectively "false" flies in the face of the reality facing the company at the time. At that point, any warnings issued to investors previously did not inoculate Mylan against materially misrepresenting the state of compliance at Morgantown. For these reasons, the Court finds that Defendants' alternative non-culpable explanations are not compelling.[10]

At this stage, the Court must not "improperly conflate pleading rules and liability rules." *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital*

[10] Defendants also argue that the lack of clear motive undermines the fraud allegations. But Plaintiff has pled a motive; according to Plaintiff, Defendants were "motivated to hide misconduct at Morgantown as they knew remediation would be costly, reduce production, and signal that CGMP violations were not isolated to Nashik." ECF 39, ¶¶ 148, 153; ECF 48, p. 57. They also "could not afford another setback after facing criticism over" numerous other issues. ECF 48, p. 57.

Inc., 531 F.3d 190, 195 (2d Cir. 2008). To survive a motion to dismiss, Plaintiff only needs to state facts "giving rise to strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). Plaintiff has met that burden.[11]

IV. Plaintiff has stated a claim for scheme liability.

Defendants next argue that "Plaintiff's claim for scheme liability under Rule 10b-5(a) and (c) fails because … Plaintiff has failed to allege an actionable misrepresentation or scienter, and therefore has not alleged any deceptive conduct." ECF 54, p. 30. In other words, according to Defendants, the scheme liability claim is entirely derivative of the misrepresentation claim.

Because the Court has found that Plaintiff has pled at least one actionable misrepresentation and scienter, Defendants' argument is not a basis to dismiss this claim, and the Court will deny the motion.

V. Plaintiff has stated a claim for control-person liability against the individual Defendants.

Finally, Defendants move to dismiss Plaintiff's claim under Section 20(a) of the Exchange Act. ECF 46, p. 60 n.30. That section provides that, "[e]very person who, directly or indirectly, controls any person[12] liable under any provision of this chapter

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[11] The Court has undergone this analysis because the amended complaint is silent on whether any of the individual Defendants participated in the drafting, delivery, or approval of the statement in the *Bloomberg Law* article. Of course, given their important roles, maybe one or all the individual Defendants were at least consulted on the content of the statement—especially considering the importance of avoiding any suggestion that Mylan had compliance issues in such a highly regulated industry. If, in discovery, it turns out that those individual Defendants were involved in making that statement, Plaintiff can seek leave to amend the amended complaint. *Winer*, 503 F.3d at 337 ("If a private securities case proceeds past the pleadings stage against a corporation and discovery reveals individual culpability, a plaintiff may seek permission to amend the complaint to assert claims against individual defendants.").

[12] "Person" also includes any entity, such that if the individual Defendants have control over a liable corporate entity (like Mylan), then they could be liable under a control-person theory of liability. *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 284 (3d Cir. 2006) ("[T]he plaintiff must prove that one person controlled another

or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable…unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action." 15 U.S.C. § 78t(a).

"Defendants' argument, however, is premised entirely on the principle that claims under Section 20(a) are derivative, and must be dismissed if the underlying Section 10(b) claim is dismissed." *Mill Bridge V, Inc. v. Benton*, No. 08-2806, 2009 WL 4639641, at *34 (E.D. Pa. Dec. 3, 2009) (cleaned up). But, as discussed above, the Court is not dismissing the Section 10(b) claims against Mylan and therefore this argument does not hold water. *Id.* Defendants "do not specifically dispute" the individual Defendants "control over [Mylan] at this stage of the proceedings," and therefore the Court finds that the statement in the *Bloomberg Law* article "is a proper predicate for establishing control person liability[.]" *Owl Creek I, L.P. v. Ocwen Fin. Corp.*, No. 18-80506, 2018 WL 4844019, at *11 (S.D. Fla. Oct. 4, 2018); *see also In re Spear & Jackson Sec. Litig.*, 399 F. Supp. 2d 1350, 1359-60 (S.D. Fla. 2005) (noting that courts "have held that allegations that individuals, because of their management and/or director positions, could control a company's general affairs, including the content of public statements … disseminated by the company, are sufficient to state a cause of action for controlling person liability" (collecting cases)).

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person ***or entity*** and that the controlled person ***or entity*** committed a primary violation of the securities laws." (emphasis added)).

CONCLUSION

For these reasons, the Court will grant in part and deny in part Defendants' motion to dismiss (ECF 45). Specifically, as discussed above, the Court has narrowed the claims at issue to the one actionable misrepresentation. The claims related to that statement in Count I of the amended complaint may proceed, but only against Defendant Mylan. The derivative control-person liability claim in Count II may proceed against the individual Defendants (Bresch, Malik, and Parks), as they relate to the actionable misrepresentation. The Court will not grant leave to amend as to the scope of the actionable statements, because the defects in the amended complaint (*i.e.*, whether certain statements are actionable) are purely legal issues, and so amendment would be futile. *See In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1332 (3d Cir. 2002). But the Court will allow Plaintiff to seek leave to amend during discovery to add back in the individual Defendants as to Count I if Plaintiff can establish their involvement as to the one remaining actionable statement at issue. *Winer*, 503 F.3d at 337. An appropriate order follows.

Date: May 18, 2023

BY THE COURT:

/s/ *J. Nicholas Ranjan*
United States District Judge